

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
Joe W. GRAY et al) Group Art Unit: 1807
Application No.: 08/487,974) Examiner: A. Marschel
Filed: June 7, 1995)
For: A METHOD OF DETECTING)
GENETIC TRANSLOCATIONS)
IDENTIFIED WITH)
CHROMOSOMAL ABNORMALITIES)
(as amended))

**INFORMATION DISCLOSURE STATEMENT
TRANSMITTAL LETTER**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

- No additional fee for submission of an IDS is required.
- The fee of \$230.00 as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- A certification under 37 C.F.R. § 1.97(e) is also enclosed.
- A certification under 37 C.F.R. § 1.97(e), a petition requesting consideration of the information disclosure statement, and the petition fee of \$130.00 as set forth in 37 C.F.R. § 1.17(i) are also enclosed.
- Charge \$_____ to Deposit Account No. 02-4800 for the fee due.
- A check in the amount of \$ 230.00 is enclosed for the fee due.

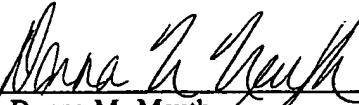
Information Disclosure Statement Transmittal Letter
Application Serial No. 08/487,974
Attorney's Docket No. 028723-016
Page 2

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in triplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____


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Date: September 4, 1997

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Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. §1.56,
Applicants hereby submit the following information in conformance with 37 C.F.R.
§§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is
enclosed.

U.S. PATENTS

4,683,202
4,755,458
5,085,983
5,427,932
5,447,841
5,472,842

FOREIGN PATENTS

0430402

OTHER DOCUMENTS

Boyle et al, "Differential Distribution of Long and Short Interspersed Element Sequences in the Mouse Genome: Chromosome Karyotyping By Fluorescence *In Situ* Hybridization," PNAS (USA), Vol. 87, Oct. 1990, pp. 7757-7761

Brock et al, "Quantitative *in situ* Hybridization Reveals Extent of Sequence Homology Between Related DNA Sequences in *Drosophila melanogaster*," CHROMOSOMA, Vol. 83, No. 2, pp. 159-168

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Bufton et al, "Four Restriction Fragment Length Polymorphisms Revealed By Probes From A Single Cosmid Map To Human Chromosome 19," Am J Hum Genet, Vol. 38, 1986, pp. 447-460

Burk et al, "Organization and Chromosomal Specificity of Autosomal Homologs of Human Y Chromosome Repeated DNA," Chromosoma, Vol. 92, 1985, pp. 225-233

Buroker et al, "Four Restriction Fragment Length Polymorphisms Revealed By Probes From A Single Cosmid Map To Human Chromosome 12q," Human Genetics, Vol. 72, 1986, pp. 86-94

Coté et al, "Quantitation of *in situ* Hybridization of Ribosomal Ribonucleic Acids to Human Diploid Cells," Chromosoma, Vol. 80, 1980, pp. 349-367

Cremer et al, "Preparative Dual-Beam Sorting of the Human Y Chromosome and *In Situ* Hybridization of Cloned DNA Probes," Cytometry, Vol. 5, 1984, pp. 572-579

Davies, "The Application of DNA Recombinant Technology to the Analysis of the Human Genome and Genetic Disease," Human Genetics, Vol. 58, 1981, pp. 351-357

Dennis et al, "Cytogenetics of the Parthenogenetic Grasshopper *Warramaba virgo* and Its Bisexual Relatives," Chromosoma, Vol. 82, 1981, pp. 453-469

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Page 3

Dutrillaux et al, "Characterization of Chromosomal Anomalies in Human Breast Cancer," Cancer Genet. Cytogenet., Vol. 49, (1990), pp. 203-217

Gerhard et al, "Localization Of a Unique Gene By Direct Hybridization *in situ*," PNAS, Vol. 78, 1981, pp. 3755-3759

Haase et al, "Detection of Two Viral Genomes in Single Cells By Double-Label Hybridization in Situ and Color Microradioautography," Science, Vol. 227, 1985, pp. 189-192

Holden et al, "Amplified Sequences from Chromosome 15, Including Centromeres, Nucleolar Organizer Regions, and Centromeric Heterochromatin, in Homogeneously Staining Regions in the Human Melanoma Cell Line MeWo," Cancer Genet. & Cytogenet., Vol. 14, 1985, pp. 131-146

Houldsworth et al, "Comparative Genomic Hybridization: An Overview," Am. J. Pathology, Vol. 145, No. 6, 1994, pp. 1253-1260

Kallioniemi et al, "Comparative Genomic Hybridization for Molecular Cytogenetic Analysis of Solid Tumors," Science, Vol. 258, 1992, pp. 818-821

Kallioniemi et al, "Optimizing Comparative Genomic Hybridization for Analysis of DNA Sequence Copy Number Changes in Solid Tumors," Genes, Chromosomes & Cancer, Vol. 10, 1994, pp. 231-243

Krumlauf et al, "Construction and Characterization of Genomic Libraries From Specific Human Chromosomes," PNAS, Vol. 79, 1982, pp. 2971-2975

Kunkel et al, "Organization and Heterogeneity of Sequences Within A Repeating Unit Of Human Y Chromosome Deoxyribonucleic Acid," Biochem., Vol. 18, 1979, pp. 3343-3353

Landegent et al, "Fine Mapping Of The Huntington Disease Linked D4S10 Locus By Non-Radioactive In Situ Hybridization," Human Genetics, Vol. 73, 1986, pp. 354-357

Lichter et al, "Fluorescence *In Situ* Hybridization with *Alu* and L1 Polymerase Chain Reaction Probes for Rapid Characterization of Human Chromosomes in Hybrid Cell Lines," PNAS (USA), Vol. 87, Sept. 1990, pp. 6634-6638

Litt et al, "A Highly Polymorphic Locus In Human DNA Revealed By Probes From Cosmid 1-5 Maps To Chromosome 2q35-37," Am J Hum Genet, Vol. 38, 1986, pp. 288-296

Litt et al, "A Polymorphic Locus On The Long Arm Of Chromosome 20 Defined By Two Probes From A Single Cosmid," Human Genetics, Vol. 73, 1986, pp. 340-345

Lux et al, "Hereditary spherocytosis associated with deletion of human erythrocyte ankyrin gene on chromosome 8," Nature, Vol. 345, June 21, 1990, pp.736-739

Malcolm et al, "Chromosomal Localization Of A Single Copy Gene By *in situ* Hybridization - Human β Globin Genes On The Short Arm Of Chromosome 11," Ann. Hum. Genet., Vol. 45, 1981, pp. 134-141

Nelson et al, "Genomic Mismatch Scanning: A New Approach To Genetic Linkage Mapping," Nature Genetics, Vol. 4, 1993, pp. 11-18

Park et al, "Amplification, Overexpression, and Rearrangement of the *erbB-2* Protooncogene in Primary Human Stomach Carcinomas," Cancer Research, Vol. 49, Dec. 1989, pp. 6605-6609

Pierce et al, "Analysis Of A Dispersed Repetitive DNA Sequence In Isogenic Lines of *Drosophila*," Chromosoma, Vol. 82, 1981, pp. 471-492

Rabin, "Mapping Minimally Reiterated Genes On Diploid Chromosomes By In Situ Hybridization," thesis, Dept. of Biochemistry, Univ. Ill., 1982

Rabin et al, "Two Homoeo Box Loci Mapped In Evolutionarily Related Mouse And Human Chromosomes," Nature, Vol. 314, 1985, pp. 175-178

Ried et al, "Direct carrier detection by *in situ* suppression hybridization with cosmid clones of the Duchenne/Becker muscular dystrophy locus," Human Genetics, Vol. 85, 1990, pp. 581-586

Ried et al, "Simultaneous Visualization of Seven Different DNA Probes by *In Situ* Hybridization Using Combinatorial Fluorescence and Digital Imaging Microscopy," PNAS (USA), Vol. 89, Feb. 1992, pp. 1388-1392

Ruddle, "A New Era In Mammalian Gene Mapping: Somatic Cell Genetics And Recombinant DNA Methodologies," Nature, Vol. 294, 1981, pp. 115-120

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Saint-Ruf et al, "Proto-Oncogene Amplification and Homogeneously Staining Regions in Human Breast Carcinomas," Genes, Chromosomes & Cancer, Vol. 2, (1990), pp. 18-26

Siracusa et al, "Use of Repetitive DNA Sequences To Distinguish *Mus musculus* and *Mus caroli* Cells By *in situ* Hybridization," J Embryol. exp. Morph., Vol. 73, 1983, pp. 163-178

Sondermeijer et al, "The Activity of Two Heat Shock Loci of *Drosophila hydei* In Tissue Culture Cells and Salivary Gland Cells as Analyzed by *in situ* Hybridization of Complementary DNA," Chromosoma, Vol. 72, 1979, pp. 281-291

Steinemann, "Multiple Sex Chromosomes in *Drosophila miranda*: A System to Study the Degeneration of a Chromosome," Chromosoma, Vol. 86, 1982, pp. 59-76

Szabo et al, "Quantitative *in Situ* Hybridization of Ribosomal RNA Species to Polytene Chromosomes of *Drosophila melanogaster*," J. Mol. Biol., Vol. 115, 1977, pp. 539-563

A fee in the amount of \$ 230.00 is enclosed in conformance with 37 C.F.R. § 1.97(c).

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialled copy of this form be returned to the undersigned.

Respectfully submitted,

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U.S. PATENT DOCUMENTS						
EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	4,683,202	7/1987	Mullis	435	91	
	4,755,458	7/1988	Rabbani et al	435		
	5,085,983	2/1992	Scanlon	435	6	
	5,427,932	6/1995	Weier et al	435	91.2	
	5,447,841	9/1995	Gray et al	435	6	
	5,472,842	12/1995	Stokke et al	435	6	
FOREIGN PATENTS DOCUMENTS						
EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	0430402	6/1991	Europe			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)						
	Boyle et al, "Differential Distribution of Long and Short Interspersed Element Sequences in the Mouse Genome: Chromosome Karyotyping By Fluorescence <i>In Situ</i> Hybridization," <i>PNAS (USA)</i> , Vol. 87, Oct. 1990, pp. 7757-7761					
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Malcolm et al, "Chromosomal Localization Of A Single Copy Gene By <i>in situ</i> Hybridization - Human β Globin Genes On The Short Arm Of Chromosome 11," <i>Ann. Hum. Genet.</i> , Vol. 45, 1981, pp. 134-141			
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